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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,258	01/18/2007	Guy Vergnault	28069-618-NATL	3154
30623	7590	09/19/2011	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C			LOVE, TREVOR M	
ONE FINANCIAL CENTER				
BOSTON, MA 02111			ART UNIT	PAPER NUMBER
			1611	
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			09/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,258	Applicant(s) VERGNAULT ET AL.	
	Examiner TREVOR LOVE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2 and 4-17 is/are pending in the application.
- 5a) Of the above claim(s) 9-11 and 15-17 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,2,4-8 and 12-14 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/29/2011 has been entered.

Claims 1, 2, 4-17 are pending.

Claims 9-11 and 15-17 remain withdrawn as being drawn to non-elect groups and/or species. See MPEP 818.01 and 818.02(a) with regard to election by original presentation.

Claims 1, 2, and 4-14 are currently under consideration.

Claim 1 is currently amended.

Withdrawn Rejections and/or Objections

The rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) is withdrawn in view of Applicant's amendments to said claims.

The rejection of claims 1 and 4-6 under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) is withdrawn in view of Applicant's amendments to said claims.

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The rejection of claims 2, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) as applied to claims 1 and 4-6 above, and further in view of Thurn-Müller et al (U.S. Patent number 5,310,578, Patent issued May 10, 1994) is withdrawn in view of Applicant's amendments to said claims.

The rejection of claims 7, 8, and 14 under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) as applied to claims 1 and 4-6 above, and further in view of Guglielmotti et al (U.S. Patent number 6,020,356, Patent issued Feb. 1, 2000) is withdrawn in view of Applicant's amendments to said claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 7, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 874,586 (IDS reference) in view of Matoba et al (U.S. Patent number 5,456,920).

GB '586 teaches a tablet comprising an active core coated with a compression coating. Said active is exemplified as being from 0.25 to 5.0 mg of prednisone (see entire document, for instance, page 6, lines 25-31). Said tablet is taught as being made by blending the powdered steroid (prednisone) with the excipients, followed by compressing, wherein said compressed core is then coated by a compression coating step (see entire document, for instance, page 2, lines 66-76). GB '586 further teaches that "dyes can be used in the tablet core and in the outer coating" (see entire document, for instance, page 3, lines 13-14).

GB '586, while teaching that a colorant can be present, and that the core is blended, fails to directly teach the instantly claimed colorant in the core.

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Matoba teaches that suitable tablet colorants include iron red oxide (see entire document, for instance, column 9, lines 11-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize iron red oxide in the core of the composition of GB '586. One would have been motivated to do so since GB '586 teaches that colorants can be utilized in the core of the composition of GB '586, and Matoba teaches that red iron oxide is a useful colorant for tablets. There would be a reasonable expectation of success since GB '586 teaches that colorants can be utilized.

Response to Arguments

Applicant's arguments are directed to rejections which are no longer of record. Therefore, Applicant's arguments are not persuasive against the new grounds of rejection set forth above.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over GB 874,586 (IDS reference) in view of Matoba et al (U.S. Patent number 5,456,920) as applied to claims 1, 2, 7, 8, and 14 above, and further in view of Sharma et al (U.S. Patent number 4,797,288).

The teachings of GB '586 and Matoba are set forth above.

GB '586, while teaching colorants are present in the core, fails to directly identify the exact amount of said colorant.

Sharma teaches that it is known to utilize up to about 1% colorant in a tablet composition (see entire document, for instance, column 11, lines 17-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize about 1% red iron oxide in the core of GB '586. One would have been motivated to do so since GB '586 teaches the use of colorant in the core without guidance as to the exact amount, and Sharma teaches that 1% is a useful amount of colorant for tablets. There would be a reasonable expectation of success since GB '586 directly teaches the use of colorants.

Response to Arguments

Applicant's arguments are directed to rejections which are no longer of record. Therefore, Applicant's arguments are not persuasive against the new grounds of rejection set forth above.

Claims 4, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 874,586 (IDS reference) in view of Matoba et al (U.S. Patent number 5,456,920) as applied to claims 1, 2, 7, 8, and 14 above, and further in view of Schopflin (U.S. Patent number 4,012,497).

The teachings of GB '586 and Matoba are set forth above.

GB '586, while teaching that excipients can be present, and that the core is blended, fails to directly teach the instantly claimed barium sulfate in the core.

Schopflin teaches an active agent composition which can be administered orally (see entire document, for instance, column 7, lines 50-54). Said composition is further taught as comprising a radiopaque amount of barium sulfate for improved x-ray localization in the body (see entire document, for instance, column 7, lines 41-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize barium sulfate in the core of GB '586. One would have been motivated to do so to improve the x-ray localization of the composition as taught by Schopflin. There would be a reasonable expectation of success since Schopflin teaches that a radiopaque amount of barium sulfate is known to improve x-ray localization in the body.

Response to Arguments

Applicant's arguments are directed to rejections which are no longer of record. Therefore, Applicant's arguments are not persuasive against the new grounds of rejection set forth above.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over GB 874,586 (IDS reference) in view of Matoba et al (U.S. Patent number 5,456,920) and Schopflin (U.S. Patent number 4,012,497) as applied to claims 1, 2, 4, 7, 8, and 12-14 above, and further in view of Schoner (U.S. Patent number 5,468,221).

The teachings of GB '586, Matoba, and Schopflin are set forth above.

GB '586 in view of Matoba and Schopflin, while teaching that a barium sulfate is present, and that the core is blended, fails to directly teach the instantly claimed amount of barium sulfate.

Schoner teaches that radiopaque components are useful for imaging within the body for localization in amounts of 1-20% (see entire document, for instance, column 3, lines 39-51).

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It would have been obvious to utilize said amount of radiopaque barium sulphate in the invention of GB '586. One would have been motivated to do so since Matoba teaches that barium sulphate is useful in amount at which it is radiopaque, and Schoner teaches that radiopaque ingredients are useful at amounts of 1-20% for imaging. There would be a reasonable expectation of success since Schoner teaches that it is known to utilize radiopaque components for imaging purposes in said amounts. It is further noted that MPEP 2144.05 states: "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997).

Response to Arguments

Applicant's arguments are directed to rejections which are no longer of record. Therefore, Applicant's arguments are not persuasive against the new grounds of rejection set forth above.

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/SHARMILA G. LANDAU/
Supervisory Patent Examiner, Art Unit 1611